

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
Spectron mrc, LLC
17490 Dugdale Drive
South Bend, Indiana 46635
REPORT NUMBER(S): 2011-001

2. NRC/REGIONAL OFFICE
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

3. DOCKET NUMBER(S)
030-38044, 030-38045

4. LICENSEE NUMBER(S)
13-32726-01MD, 13-32726-02

5. DATE(S) OF INSPECTION
Sept. 1, 2011

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied

_____ Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Geoffrey M. Warren	<i>G. Warren</i>	9/1/11
Branch Chief	Tamara E. Bloomer	<i>T. Bloomer</i>	9/19/11

Docket File Information
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6. INSPECTION PROCEDURES
87127, 87125

7. INSPECTION FOCUS AREAS
03.01 – 03.07, 03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM
02500, 03210

2. PRIORITY
2, 2

3. LICENSEE CONTACT
Kirk Rozycki, R.Ph., RSO

4. TELEPHONE NUMBER
574-271-2800

☒ Main Office Inspection

Next Inspection Date: Sept. 2013

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This licensee operated a cyclotron for production of fluorine-18 (F-18) and a radiopharmacy for production of F-18 FDG and distribution to clients. This radiopharmacy employed two pharmacists, one chemist, three cyclotron operators, and nine drivers. The licensee had seven regular customers located in northern Indiana and southwestern Michigan, and distributed approximately 40 to 45 doses each day. The pharmacy was open weekdays from midnight to 4:00 pm. Two cyclotron runs were scheduled daily, ending at around 4:00 and 7:00 am. Shipments left the facility at around 5:30 and 8:30 am, and as needed after then. The maximum dose received by licensee personnel in 2010 was 4.1 rem whole body and 29.8 rem extremity; this individual, a cyclotron engineer, was tracked and his duties ended for the year once his whole-body dose exceeded 4 rem. For January through July 2011, the maximum doses received were 2.1 rem whole body and 10.9 rem extremity.

Performance Observations

The inspector observed chemistry setup, hot cell cleaning/sterilization, F-18 receipt from the cyclotron, dose preparation, sample QC, dose packaging and survey, dose tracking, package surveys and wipes, shipping paper preparation, package blocking and bracing, daily surveys, weekly wipes, and package return surveys. Licensee personnel demonstrated dose calibrator constancy, vehicle surveys, and other procedures, and described cyclotron maintenance. The inspector noted no concerns with these activities. The inspector observed that the licensee used remote systems and a hot cell for dose preparation and proper shielding for doses removed from the hot cell. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.